K010756

APR 1 2 2001

510(k) Summary

March 06, 2001

Submitter: Cambridge Heart, Inc
1 Oak Park
Bedford, Ma 01730
(781) 271-1200
(781) 275-8431

Contact: Dave Chazanovitz

510(k) Numbers and Product Codes of equivalent devices:

Cambridge Heart, Inc.; Alternans Processing System

510(k) Number: #K003492

Product Code: 74 DPS

CFR Section: 870.2340

Cambridge Heart, Inc.; Model CH 2000 Cardiac Diagnostic System

510(k) Number: #K983102

Product Code: 74 DPS

CFR Section: 870.2340

Indications for Use and Intended Population

The Model CH 2000 Cardiac Diagnostic System is intended for the recording of electrocardiograms, vector cardiograms and measurement of Microvolt T-Wave Alternans* at rest and during ECG stress testing.

The presence of Microvolt T-wave Alternans as measured by the analytic spectral method of the Model CH 2000 Cardiac Diagnostic System in patients with known, suspected or at risk of ventricular tachyarrhythmia predicts increased risk of a cardiac event (ventricular tachyarrhythmia or sudden death).

The Cambridge Heart Model CH 2000 Cardiac Diagnostic System should be used only as an adjunct to clinical history and the results of other non-invasive and/or invasive tests.

The predictive value of T-wave Alternans for cardiac events has not been established in patients with active, untreated ischemia.

*Microvolt T-wave Alternans is defined as T-wave alternans which (a) is measured from high-resolution multi-segment sensors, (b) is present in leads X, Y, Z, VM or two adjacent precordial leads, (c) is at the level of 1.9 microvolts after signal optimization and subtraction of the background noise level, (d) is at least three standard deviations

greater than the background noise level, (e) has an onset heart rate at or below 110 beats per minute, and (f) is sustained for all heart rates above the onset heart rate.

Device Description

The Cambridge Heart Model CH 2000 Cardiac Diagnostic System is intended for the measurement and recording of T-Wave alternans. The alternans levels reported in K983012, K001034 and K003492 were measured using the Analytic Spectral Method. This method consists of several computational steps that combine to form a unique analytical process. The Microvolt T-wave Alternans measurement, the output of this specific process, has been shown to be useful in predicting ventricular tachyarrhythmias and sudden cardiac death.

The Cambridge Heart Model CH 2000 Cardiac Diagnostic System provides T-wave alternans diagnostic capabilities to standard stress labs. The Analytic Spectral Method of Alternans Processing used in the Cambridge Heart Model CH 2000 is intended for the measurement of microvolt T-Wave alternans at rest and during treadmill, ergometer and pharmacologic stress testing.

The Alternans test using the Cambridge Heart Model CH 2000 is performed with seven standard stress test electrodes and seven proprietary multi-segment Micro-V Alternans™ Sensors. The electrodes and sensors are attached through a leadwire set to the belt-worn Patient module, which provides digitized data to the CH 2000.

Patient Electrodes:

Patient electrodes designed and approved specifically for use during exercise stress testing should be used at all times with the Cambridge Heart Model CH 2000 Cardiac Diagnostic System.

Measurement of alternating beat to beat T-wave amplitude (alternans) requires the use of the Cambridge Heart Hi-Res Electrode (Ref: # K962115) or The Cambridge Heart Micro-V Alternans Sensor (Ref: #K002230) in conjunction with other Patient electrodes designed and approved specifically for use during exercise stress testing.

Performance Standards

The Cambridge Heart Model CH 2000 Cardiac Diagnostic System meets the following Performance Standards:

ANSI/AAMI EC11-1991

EN60601-1: 1988, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including Amendments A1 and A2

EN60601-1-1: 1993, "Medical Electrical Equipment, Part 1: General Requirements for Safety - Section 1.1 Collateral standard: Safety requirements for medical electrical systems"

EN60601-1-2: 1993, "Medical Electrical Equipment, Part 2: Collateral Standard:

Electromagnetic Compatibility – Requirements and Tests"

UL2601-1, "Medical Electrical Equipment, Part 1: General Requirements for Safety" 2nd Edition, including Amendments A1 and A2

CAN/CSA C22.2 No. 601.1-M90, "Medical Electrical Equipment, Part 1: General Requirements for Safety" including C22.2 No. 601.1S1-94 (IEC 601-1, Amendment 1:1991)

Conclusion

There are more similarities than differences between the predicate device and the Cambridge Heart Model CH 2000 Cardiac Diagnostic System. Both the predicate devices use the Analytic Spectral Method of Alternans Processing. When used in accordance with the directions for use, by qualified personnel, the Cambridge Heart Model CH 2000 Cardiac Diagnostic System is safe and effective, as indicated, for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 1 2 2001

Cambridge Heart, Inc.
c/o Mr. John Greenbaum
Generic Devices Consulting
20310 SW 48th Street
Ft. Lauderdale, FL 33332

Re: K010756
Trade Name: CH 2000 Cardiac Diagnostic System
Regulatory Class: II (two)
Product Code: 74 DQK
Dated: March 6, 2001
Received: March 13, 2001

Dear Mr. Greenbaum:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might

have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number(if known): K010756

Device Name: Model CH 2000 Cardiac Diagnostic System

Indications For Use:

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PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use_X_ OR Over-The-Counter Use___
(Per 21 CRF 801.109)

(Optional Format 1-2-96)

Division of Cardiovascular & Respiratory Devices
510(k) Number K010756